

### **REMARKS/ARGUMENTS**

Claims 1, 3, 7, 24 and 25 are pending in this application. Claims 2, 4-6, 8-23 and 2-27 have been previously cancelled.

#### **35 U.S.C. §103 Rejections**

Claims 1, 3, 7 and 24-25 are rejected under 35 U.S.C. §103(a) as obvious over the combined teachings from Schroder, (1942, "Die Venwendung der Susswasserschwamme in der Ukraine" Die 3, Umschau Wissenschaft Technik 46: 507-509) ("Schroder") (Applicant provides a full English translation of this document attached) in view of Philippe et al. (US Pat. 7,078,047) ("Philippe"). Applicant disagrees with the aforementioned rejection for the following reasons.

Obviousness is a question of law based on underlying findings of fact. An obviousness rejection is appropriate when the subject matter sought to be patented, as a whole and in light of the prior art, would have been obvious to a person of ordinary skill in the art at the time of the invention. 35 U.S.C. § 103 (2008). An analysis of obviousness must be based on several factual inquiries: (1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; (3) the level of ordinary skill in the art at the time the invention was made; and (4) objective evidence of nonobviousness, if any. *See Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966). Support for any 35 U.S.C. § 103 rejection must include a "clear articulation of the reason(s) why the claimed invention would have been obvious." M.P.E.P. § 2142, citing *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 418, 82 USPQ2d 1385, 1396 (2007). The Office bears the initial burden of factually supporting a *prima facie* conclusion of obviousness, and if the examiner does not meet this burden, the applicant is "under no obligation to submit evidence of nonobviousness." M.P.E.P. § 2142.

In the present case, the teachings of Schroder in view of Philippe do not teach all the limitations presently claimed. To establish *prima facie* obviousness of a claimed

invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (C.C.P.A. 1974) (emphasis added). Furthermore, "All the words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (C.C.P.A. 1970). The present claims recite substantially pure *S. lacustris* compositions, having from 50% to 60% insoluble material with a maximum particle size of 0.2 mm. The combined teachings of Schroder and Philippe do not teach or suggest the compositions of the present application including all their limitations.

First, Schroder does not teach compositions comprising a substantially pure powder of *Spongia lacustris* (*S. lacustris*). Schroder specifically teaches the use of "the sponge drug, called badiaga or *Spongia fluviatilis*" (*S. fluviatilis*) (Schroder, German document and attached English translation p. 507, col. 2) (*S. fluviatilis* is also referred to by the native population as "nadoshnik" or "ladoshnik" or "ladeshnik," see Schroder, German document and attached English translation p. 509, col. 1-2) for a variety of applications ranging from a liniment to treat pain to internal application to treat rheumatism and dropsy to use as makeup (Schroder, German document and attached English translation p. 508, col. 1). *S. lacustris* is only mentioned in Schroder's figures 3 and 4, which depict *S. lacustris* on masonry and wool thread, respectively. (Schroder, German document and attached English translation p. 507). The article does not teach or suggest any compositions comprising *S. lacustris*. The entire publication focuses on "the sponge drug" or badiaga, which the article specifically defines as *S. fluviatilis*. Thus, Schroder does not teach or suggest, as the Office contends, "a powder of fresh water sponges, wherein one of the sponge [sic] is *Spongia lacustris*."

Moreover, an ordinary skilled artisan would not have found it obvious to replace *S. fluviatilis* as taught in Schroder with *S. lacustris*. *S. lacustris* is a specific and distinguishable species of fresh water sponges, with distinct characteristics. To analogize, *Penicillium chrysogenum* is a distinct species of the genus *Penicillium*, and is the main source of several antibiotics. Several other species of *Penicillium* exist but they exhibit different properties and are not useful as a source of antibiotic. A skilled

artisan in the relevant field would expect different species of *Penicillium* to exhibit different properties. Here, similarly, a person skilled in the art would have known that over 150 different species of fresh water sponges exist, each exhibiting its own unique characteristics. Such a person would not have found it obvious, without any suggestion or motivation, to substitute Schroder's *S. fluviatilis* with *S. lacustris*.

Second, Schroder does not teach or suggest compositions having approximately 50% to 60% insoluble material. The only composition Schroder discloses is a tincture consisting of "10 parts badiaga [or *S. fluviatilis*] and 90 parts alcohol or petroleum." A tincture consisting of 10 parts *S. fluviatilis* and 90 part alcohol is markedly different than a substantially pure *S. lacustris* composition, having from 50% to 60% insoluble material. In an attempt to find some correlations between the cited art and the present application, the Office mischaracterizes both the teachings of Schroder and the present claims. The Office contends, "the fresh water sponge powder of the prior art would inherently have the same properties (i.e., approximately 50-60% insoluble material and a maximum particle size of 0.2 mm) as instantly claimed because the prior art composition is comprised of same [*sic*] components prepared in the same way as the claimed composition." (March 18, 2009 Office Action, p. 3). However, the fresh water sponge taught in Schroder is *S. fluviatilis*, not *S. lacustris* as is presently claimed. Further, the present claims recite therapeutic compositions of *S. lacustris* comprising approximately 50-60% insoluble material. Schroder does not disclose any *S. lacustris* composition, and thus, definitely does not disclose the same therapeutic composition as is presently claimed.

To refresh the Office's memory on patent law and the theory of inherency, "The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." M.P.E.P. § 2112 (IV); citing *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (emphasis in original). "To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." M.P.E.P. §

2112 (IV); *citing In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (emphasis added). As the Manual of Patent Examining Procedure (M.P.E.P.) and the Board of Patent Appeals and Interferences (B.P.A.I.) have made abundantly clear, "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." M.P.E.P. § 2112; *citing Ex parte Levy*, 17 USPQ2d 1461, 1464 (B.P.A.I. 1990) (emphasis in original).

In the instant case, the Office has not provided any support for its inherency argument. The Office has not shown how the use of a folk medicine tincture consisting of 10 parts *S. fluviatilis* and 90 parts alcohol or petroleum "would inherently have the same properties" as the presently-claimed, substantially pure *S. lacustris* compositions, having from 50% to 60% insoluble material with a maximum particle size of 0.2 mm.

Third, Schroder does not teach or suggest a maximum particle size of 0.2 mm. With disregard of the actual teachings of the cited art, the Office contests that the powder of the fresh water sponge is "obtained by comminuting said fresh water sponge... Note comminution would produce powder having a particle size of up to 0.2 mm." (March 18, 2009 Office Action, p. 3). However, this conclusion again misrepresents the teachings of the cited art. Schroder teaches grinding the "the sponge drug" or *S. fluviatilis* between the fingers to create a powder. (Schroder, German document and attached English translation p. 507, col. 2 – p. 508, col. 1). Schroder does not teach specific particle sizes and the Office does not explain how it has reached the conclusion that grinding between the fingers "would produce powder having a particle size of up to 0.2 mm."

Philippe does not remedy the deficiencies of Schroder. Philippe does not teach or fairly suggest a composition comprising a substantially pure powder of *S. lacustris*, having approximately 50-60% insoluble material with a maximum particle size of 0.2

mm. Additionally, nothing in Philippe would suggest modifying the Schroder teachings to arrive at the presently claimed compositions.

As the Supreme Court explained in *KSR*, to support a conclusion of obviousness, the Office must show that all the claimed elements were known in the prior art and that a person of ordinary skill in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination yields nothing more than predictable results to a person of ordinary skill in the arts. *KSR*, 550 U.S. at 415-16, 82 USPQ2d at 1394. In the instant case, the combined references, Schroder in view of Philippe, fail to teach or suggest the presently claimed compositions and their claimed limitations. The Office has failed to meet its *prima facie* burden of factually supporting its conclusion of obviousness because it has not shown how the subject matter as a whole would have been obvious to a person having ordinary skill in the relevant art.

Moreover, Applicant notes that Schroder's validity as a "printed publication" within the meaning of 35 U.S.C. § 102(a) and (b) is questionable, at best. "A reference is proven to be a 'printed publication' 'upon a satisfactory showing that such document has been disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, can locate it.'" M.P.E.P. § 2128; *citing In re Wyer*, 655 F.2d 221, 210 USPQ 790 (C.C.P.A. 1981).

Schroder was printed in 1942 in the science periodical "Die Umschau Wissenschaft Technik." German science periodicals published during World War II, such as the one in which Schroder was published, are not well disseminated and are extremely hard to find. It is unlikely that a person of ordinary skill in the relevant field would seek a Nazi reference that explicitly pays tribute to the German army and its conquest of Ukraine (Schroder, German document and attached English translation p. 507, col. 2), and that cites experiments conducted on human prisoners in Nazi concentration camps (Schroder, German document and attached English translation p.

509, Fig. 12 and 13). Such experiments were often brutal crimes committed under the guise of Nazi medicine and their contributions to the field of science have been questioned for years. Thus, similar to other art the Office has previously cited in this case, Schroder is questionable as 35 U.S.C. § 102 prior art.

For the reasons detailed above, Applicant asserts that the Office has not established a *prima facie* case of obviousness and respectfully request that the 35 U.S.C. §103(a) rejections of record as to claims 1, 3, 7, 24 and 25 be withdrawn.

Applicant further requests that a timely Notice of Allowance be issued in this case. The Commissioner is authorized to charge any fee which may be required in connection with this Amendment to deposit account No. 50-3207.

Respectfully submitted,

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/Sara Kerrane/  
Sara Kerrane  
Registration No. 62801  
CUSTOMER NUMBER: 45,200

**K&L GATES LLP**  
1900 Main Street, Suite 600  
Irvine, California 92614-7319  
Telephone: (949) 253-0900  
Facsimile: (949) 253-0902